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## I. STATUS OF CLAIMS

Claims 1-34 were pending at the time of this office action. Claims 1, 15 and 16 have been amended. Claims 66-68 are newly presented. No new matter was added and support for the claim amendments can be found in at least figure 3 and its associated description. Claims 1-34 and 66-68 remain pending.

Applicant's priority claim stands objected as being improper. *See Examiner's Office Action*, p. 2 (23 June 2009).

The drawings stand objected to as being informal and difficult to read and/or interpret. *See Examiner's Office Action*, p. 2 (23 June 2009).

The terminal disclaimers filed March 26, 2008 stand objected for being signed by an unauthorized attorney. *See Examiner's Office Action*, p. 3 (23 June 2009).

Claims 1-34 stand provisionally rejected for non-statutory obviousness-type double patenting over claims of co-pending Application Nos. 10/827,576 and 10/827,390. *See Examiner's Office Action*, p. 9 (23 June 2009).

Claims 1-8, 17, 20, 21, 25-30, and 32-34 stand rejected under 35 U.S.C. §102(b) as being anticipated by Lebel et al. (U.S. Publication 2002/0065509 A1) ("Lebel"). *See Examiner's Office Action*, p. 4 (23 June 2009).

Claims 1-8, 17, 20, 21, 25-30, and 32-34 stand rejected under 35 U.S.C. §102(b) as being anticipated by Labbe et al. (U.S. Patent 4,944,659) ("Labbe"). *See Examiner's Office Action*, p. 5 (23 June 2009).

Claims 1, 10-14, 18, 19, 23, and 24 stand rejected under 35 U.S.C. §102(b) as being anticipated by Davison et al. (U.S. Patent 6,296,638) ("Davison"). *See Examiner's Office Action*, p. 5 (23 June 2009).

Claims 1 and 22 stand rejected under 35 U.S.C. §102(b) as being anticipated by Adair (U.S. Patent 6,086,528) ("Adair"). *See Examiner's Office Action*, p. 6 (23 June 2009).

Claims 9 and 31 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Lebel. *See Examiner's Office Action*, p. 7 (23 June 2009).

Claims 9 and 31 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Labbe. *See Examiner's Office Action*, p. 7 (23 June 2009).

Claims 15 and 16 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Lebel or Labbe in view of Stultz (U.S. Patent Publication 2002/0156462 A1) (“Stultz”). *See Examiner’s Office Action*, p. 7 (23 June 2009).

## **II. PRIORITY CLAIM OBJECTION**

Applicant’s priority claim stands objected as being improper. *See Examiner’s Office Action*, p. 2 (23 June 2009). Examiner stated that Applicant has not properly claimed priority to any application listed at the beginning of the specification. Applicant respectfully traverses the objection on the grounds that the preliminary amendment filed March 9, 2007 includes proper cross-references to related applications.

## **III. DRAWINGS OBJECTION**

The drawings stand objected to as being informal and difficult to read and/or interpret. *See Examiner’s Office Action*, p. 2 (23 June 2009). Applicant hereby provides corrected drawing sheets in compliance with 37 CFR §1.121(d) and respectfully requests reconsideration and removal of the objection.

## **IV. DOUBLE PATENTING REJECTION**

Claims 1-34 stand provisionally rejected for non-statutory obviousness-type double patenting over claims of co-pending Application Nos. 10/827,576 and 10/827,390. *See Examiner’s Office Action*, p. 9 (23 June 2009).

A timely filed terminal disclaimer in compliance with 37 CFR §1.321(c) or §1.321(d) may be used to overcome an actual or provisional rejection based on nonstatutory double patenting provided the conflicting applications or patents are shown to be commonly owned.

Applicant hereby files concurrently herewith a terminal disclaimer in compliance with 37 CFR §1.321(c) or §1.321(d) and affirms that the present application and Application Serial Nos. 10/827,576 and 10/827,390 are commonly owned.

Accordingly, Applicant respectfully submits that the provisional non-statutory obvious-type double patenting rejection has been overcome. In light of overcoming this rejection and the

remarks set forth below, Applicant respectfully requests reconsideration and allowance of all pending claims.

## **V. ISSUES TO BE REVIEWED**

The issues in this response relate to whether the art of record establishes a *prima facie* case of the unpatentability of Applicant's claims. For reasons set forth elsewhere herein, Applicant respectfully asserts that the art of record does not establish a *prima facie* case of the unpatentability of any pending claim.<sup>1</sup> Accordingly, Applicant respectfully requests that Examiner hold all pending claims allowable for at least the reasons described herein, and issue a Notice of Allowance on same.

## **VI. ARGUMENT: ART OF RECORD DOES NOT ESTABLISH PRIMA FACIE CASE OF UNPATENTABILITY IN VIEW OF CITED ART OF RECORD**

Applicant respectfully asserts herein that, under the MPEP and legal standards for patentability as set forth below, the art of record does not establish a *prima facie* case of the unpatentability of Applicant's claims at issue. Specifically, Applicant respectfully shows below that the cited art of record *prima facie* does not recite the text of Applicant's claims at issue, no linking evidence sufficient to cure the *prima facie* differences between cited art and Applicant's claims at issue has been adduced, and hence the cited art fails to establish a *prima facie* case of unpatentability of Applicant's claims at issue. Accordingly, Applicant respectfully requests that the Examiner withdraw her rejections and hold all claims to be allowable over the art of record.

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<sup>1</sup> Irrespective of a desire to be cooperative, the ability of any patent practitioner to help the Examiner fulfill this burden on the record is tightly curtailed by pre- and post-issuance legal standards and by various ethical duties in tension. *See, e.g.*, 37 C.F.R. § 10.83 ("A practitioner should represent a client zealously within the bounds of the law."); 37 C.F.R. § 10.84 ("[A] practitioner shall not intentionally ... [p]rejudice or damage a client during the course of a professional relationship, except as required under this [ethics] part."); and 37 C.F.R. § 10.76 ("A practitioner should represent a client competently."). For these and other reasons, this document notes instances in which the Examiner inadvertently did not follow the prescribed rules rather than seeking to interpret claims and/or to adduce evidence on the Examiner's behalf.

## A. MPEP Standards for Patentability<sup>2</sup>

The MPEP states as follows: “the examiner bears the initial burden, on review of the prior art or on any other ground, of presenting a *prima facie* case of unpatentability. If that burden is met, the burden of coming forward with evidence or argument shifts to the applicant. . . If examination at the initial stage does not produce a *prima facie* case of unpatentability, then without more the applicant is entitled to grant of the patent.” *MPEP* § 2107 (citing *In re Oetiker*, 977 F.2d 1443, 1445, 24 U.S.P.Q.2d 1443, 1444 (Fed. Cir. 1992)); *In Re Glaug* 283 F.3d 1335, 62 USPQ2d 1151 (Fed. Cir. 2002) (“During patent examination the PTO bears the initial burden of presenting a *prima facie* case of unpatentability. *In re Oetiker*, 977 F.2d 1443, 1445, 24 U.S.P.Q.2d 1443, 1444 (Fed. Cir. 1992); *In re Piasecki*, 745 F.2d 1468, 1472, 223 U.S.P.Q. 785, 788 (Fed. Cir. 1984). If the PTO fails to meet this burden, then the applicant is entitled to the patent.”). Accordingly, unless and until an examiner presents evidence establishing *prima facie* unpatentability, an applicant is entitled to a patent on all claims presented for examination.

### 1. MPEP Standards for Determining Anticipation

An examiner bears the initial burden of factually supporting any *prima facie* conclusion of anticipation. *Ex Parte Skinner*, 2 U.S.P.Q.2d 1788, 1788-89 (B.P.A.I. 1986); *In Re King*, 801 F.2d 1324, 231 U.S.P.Q. (BNA) 136 (Fed. Cir. 1986); *MPEP* § 2107 (citing *In re Oetiker*, 977 F.2d 1443, 1445, 24 U.S.P.Q.2d 1443, 1444 (Fed. Cir. 1992) (“[T]he examiner bears the initial burden, on review of the prior art or on any other ground, of presenting a *prima facie* case of unpatentability....”)). Failure of an examiner to meet this burden entitles an applicant to a patent. *Id.* (“[i]f examination at the initial stage does not produce a *prima facie* case of unpatentability, then without more the applicant is entitled to grant of the patent”).

The MPEP indicates that in order for an examiner to establish a *prima facie* case of anticipation of an applicant’s claim, the examiner must first interpret the claim,<sup>3</sup> and thereafter

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<sup>2</sup> Applicant is aware that Examiner is familiar with the MPEP standards. Applicant is merely setting forth the MPEP standards to serve as a framework for Applicant’s arguments following and to ensure a complete written record is established. Should Examiner disagree with Applicant’s characterization of the MPEP standards, Applicant respectfully requests correction.

<sup>3</sup> With respect to interpreting a claim at issue, the MPEP directs that, during examination -- as opposed to subsequent to issue -- such claim be interpreted as broadly as the claim terms would reasonably allow, in light of the specification, when read by one skilled in the art with which the claimed invention is most closely connected. *MPEP* § 2111.

show that the cited prior art discloses the same elements, in the same arrangement, as the elements of the claim which the examiner asserts is anticipated. More specifically, the MPEP states that “[a] claim is anticipated *only if each and every element as set forth in the claim is found*, either expressly or inherently described, in a single prior art reference. . . . The identical invention must be shown in as complete detail as is contained in the . . . claim. . . . The elements must be arranged as required by the claim . . . .” *MPEP* § 2131 (emphasis added). Consequently, under the guidelines of the MPEP set forth above, if there is *any* substantial difference between the prior art cited by an examiner and an applicant’s claim which the examiner asserts is rendered anticipated by the prior art, the prior art does NOT establish a *prima facie* case of anticipation and, barring other rejections, the applicant is entitled to a patent on such claim.

## 2. MPEP Standards for Determining Obviousness

“[T]he examiner bears the initial burden of factually supporting any *prima facie* conclusion of obviousness.”<sup>4</sup> *MPEP* § 2142. The MPEP indicates that in order for an examiner to establish a *prima facie* case that an invention, as defined by a claim at issue, is obvious, the examiner must (1) interpret the claim at issue; (2) define one or more prior art reference components relevant to the claim at issue; (3) ascertain the differences between the one or more prior art reference components and the elements of the claim at issue; and (4) adduce objective evidence which establishes, under a preponderance of the evidence standard, a teaching to modify the teachings of the prior art reference components such that the prior art reference components can be used to construct a device substantially equivalent to the claim at issue. This last step generally encompasses two sub-steps: (1) adducement of objective evidence teaching how to modify the prior art components to achieve the individual elements of the claim at issue; and (2) adducement of objective evidence teaching how to combine the modified individual components such that the claim at issue, as a whole, is achieved. *MPEP* § 2141; *MPEP* § 2143. Each of these forgoing elements is further defined within the MPEP. *Id.*

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<sup>4</sup> An invention, as embodied in the claims, is rendered obvious if an examiner concludes that although the claimed invention is not identically disclosed or described in a reference, the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. *MPEP* § 2141 (citing 35 U.S.C. § 103).

This requirement has been explained recently by the Supreme Court in *KSR v. Teleflex*, 550 U.S. \_\_\_\_; 127 S. Ct. 1727 (2007) which noted that such a rejection requires “some articulated reasoning … to support the legal conclusion of obviousness.” As stated by the Court, obviousness can be established where “there was an apparent reason to combine the known elements in the fashion claimed by the patent at issue. To facilitate review, *this analysis should be made explicit.*” (emphasis added). *See In re Kahn*, 441 F. 3d 977, 988 (CA Fed. 2006) (‘[R]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.’).” *KSR v. Teleflex*, 550 U.S. \_\_\_\_; 127 S. Ct. 1727 at 1741.

As further described by the Court “*[A] patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art.* Although common sense directs one to look with care at a patent application that claims as innovation the combination of two known devices according to their established functions, it can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does. This is so because inventions in most, if not all, instances rely upon building blocks long since uncovered, and claimed discoveries almost of necessity will be combinations of what, in some sense, is already known.” *KSR v. Teleflex*, 550 U.S. \_\_\_\_; 127 S. Ct. 1727 at 1741.

#### a) Interpreting a Claim at Issue

With respect to interpreting a claim at issue, the MPEP directs that, during examination -- as opposed to subsequent to issue -- such claim be interpreted as broadly as the claim terms would reasonably allow when read by one skilled in the art with which the claimed invention is most closely connected. In practice, this is achieved by giving each of the terms in the claim the “plain meaning” of the terms as such would be understood by those having ordinary skill in the art, and if portions of the claim have no “plain meaning” within the art, or are ambiguous as used in a claim, then the examiner is to consult the specification for clarification. *MPEP* § 2111.

**b) Definition of One or More Prior Art Reference Components Relevant to the Claim at Issue**

Once the claim at issue has been properly interpreted, the next step is the definition of one or more prior art reference components (e.g., electrical, mechanical, or other components set forth in a prior art reference) relevant to the properly interpreted claim at issue. With respect to the definition of one or more prior art reference components relevant to the claim at issue, the MPEP defines three proper sources of such prior art reference components, with the further requirement that each such source must have been extant at the time of invention to be considered relevant. These three sources are as follows: patents as defined by 35 U.S.C. § 102, printed publications as defined by 35 U.S.C. § 102, and information (e.g., scientific principles) deemed to be “well known in the art”<sup>5</sup> as defined under 35 U.S.C. § 102. *MPEP* § 2141; *MPEP* § 2144.

**c) Ascertainment of Differences between Prior Art Reference Components and Claim at Issue; Teaching to Modify and/or Combine Prior Art Reference Components to Remedy Those Differences in Order to Achieve Recitations of Claim at Issue**

With one or more prior art components so defined and drawn from the proper prior art sources, the differences between the one or more prior art reference components and the elements of the claim at issue are to be ascertained. Thereafter, in order to establish a case of *prima facie* obviousness, an examiner must set forth a rationale, supported by objective evidence<sup>6</sup> sufficient to demonstrate under a preponderance of the evidence standard, that in the prior art extant at the time of invention there was a teaching to modify and/or combine the one or more prior art reference components to construct a device practicably equivalent to the claim at issue.

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<sup>5</sup> The fact that information deemed to be “well known in the art” can serve as a proper source of prior art reference components seems to open the door to subjectivity, but such is not the case. As a remedy to this potential problem, *MPEP* § 2144.03 states that if an examiner asserts that her position is derived from and/or is supported by a teaching or suggestion that is alleged to have been “well known in the art,” and that if an applicant traverses such an assertion (that something was “well known within the art”), the examiner must cite a reference in support of his or her position. The same MPEP section also states that when a rejection is based on facts within the personal knowledge of an examiner, the data should be stated as specifically as possible, and the facts must be supported, when called for by the applicant, by an affidavit from the examiner. Such an affidavit is subject to contradiction or explanation by the affidavits of the applicant and other persons. *Id.* Thus, all sources of prior art reference components must be objectively verifiable.

<sup>6</sup> The proper sources of the objective evidence supporting the rationale are the defined proper sources of prior art reference components, discussed above, with the addition of factually similar legal precedent. *MPEP* § 2144.

The preferable evidence relied upon is an express teaching to modify/combine within the properly defined objectively verifiable sources of prior art. In the absence of such express teaching, an examiner may attempt to establish a rationale to support a finding of such teaching reasoned from, or based upon, express teachings taken from the defined proper sources of such evidence (*i.e.*, properly defined objectively verifiable sources of prior art). *MPEP* § 2144; *In re Dembicczak*, 50 U.S.P.Q.2d 1614 (Fed. Cir. 1999).

The MPEP recognizes the pitfalls associated with the tendency to subconsciously use impermissible “hindsight” when an examiner attempts to establish such a rationale. The MPEP has set forth at least two rules to ensure against the likelihood of such impermissible use of hindsight. The first rule is that:

under 35 U.S.C. 103, the examiner must step backward in time and into the shoes worn by the hypothetical “person of ordinary skill in the art” when the invention was unknown and just before it was made. In view of all factual information,<sup>7</sup> the examiner must then make a determination whether the claimed invention “as a whole” would have been obvious at that time to that person. Knowledge of an Applicant’s disclosure must be put aside in reaching this determination, yet kept in mind in order to determine the “differences,” conduct the search, and evaluate the “subject matter as a whole” of the invention. The tendency to resort to “hindsight” based upon an Applicant’s disclosure is often difficult to avoid due to the very nature of the examination process. However, impermissible hindsight must be avoided and the legal conclusion must be reached on the basis of the facts gleaned from the prior art.

*MPEP* § 2142 (emphasis added). Thus, if the only objective evidence of such teaching to modify and/or combine prior art reference components is an applicant’s disclosure, no evidence of such teaching exists.<sup>8</sup>

The second rule is that if an examiner attempts to rely on some advantage or expected beneficial result that would have been produced by a modification and/or combination of the prior art reference components as evidence to support a rationale to establish such teachings to

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<sup>7</sup> “Factual information” is information actually existing or occurring, as distinguished from mere supposition or opinion. *Black’s Law Dictionary* 532 (5th ed. 1979).

<sup>8</sup> An applicant may argue that an examiner’s conclusion of obviousness is based on improper hindsight reasoning. However, “[a]ny judgment on obviousness is in a sense necessarily a reconstruction based on hindsight reasoning, but so long as it takes into account only knowledge which was within the level of ordinary skill in the art at the time the claimed invention was made and does not include knowledge gleaned only from applicant’s disclosure, such a reconstruction is proper.” *MPEP* § 2145(X)(A) (emphasis added).

modify and/or combine prior art reference components, the MPEP requires that such advantage or expected beneficial result be objectively verifiable teachings present in the acceptable sources of prior art (or drawn from a convincing line of reasoning based on objectively verifiable established scientific principles or teachings). *MPEP* § 2144. Thus, as a guide to avoid the use of impermissible hindsight, these rules from the MPEP make clear that absent some objective evidence, sufficient to persuade under a preponderance of the evidence standard, no teaching of such modification and/or combination exists.<sup>9</sup>

**B. Technical Material Cited by Examiner Prima Facie Does Not Show/Suggest Recitations of Independent Claim 1 and Dependent Claims 2-34 and 66-68 as Presented Herein; Notice of Allowance of Same Respectfully Requested**

**1. Independent Claim 1**

Independent Claim 1 recites as follows:

1. A device for perfusion management, comprising:

[a] a body portion;

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<sup>9</sup> *In Re Sang Su Lee* 277 F.3d 1338 (Fed. Cir. 2002) (“When patentability turns on the question of obviousness, the search for and analysis of the prior art includes evidence relevant to the finding of whether there is a teaching, motivation, or suggestion to select and combine the references relied on as evidence of obviousness.”) *See, e.g., McGinley v. Franklin Sports, Inc.*, 262 F.3d 1339, 1351-52, 60 U.S.P.Q.2d 1001, 1008 (Fed. Cir. 2001) (“the central question is whether there is reason to combine [the] references,” a question of fact drawing on the *Graham* factors). “*The factual inquiry whether to combine references must be thorough and searching.*” *Id.* *It must be based on objective evidence of record. This precedent has been reinforced in myriad decisions, and cannot be dispensed with.* *See, e.g., Brown & Williamson Tobacco Corp. v. Philip Morris Inc.*, 226 F.3d 1120, 1124-25, 56 U.S.P.Q.2d 1456, 1459 (Fed. Cir. 2000) (“a showing of a suggestion, teaching, or motivation to combine the prior art references is an essential component of an obviousness holding”) (quoting *C.R. Bard, Inc. v. M3 Systems, Inc.*, 157 F.3d 1340, 1352, 48 U.S.P.Q.2d 1225, 1232 (Fed. Cir. 1998)); *In re Dembiczak*, 175 F.3d 994, 999, 50 U.S.P.Q.2d 1614, 1617 (Fed. Cir. 1999) (“Our case law makes clear that the best defense against the subtle but powerful attraction of a hindsight-based obviousness analysis is rigorous application of the requirement for a showing of the teaching or motivation to combine prior art references.”); *In re Dance*, 160 F.3d 1339, 1343, 48 U.S.P.Q.2d 1635, 1637 (Fed. Cir. 1998) (there must be some motivation, suggestion, or teaching of the desirability of making the specific combination that was made by the applicant); *In re Fine*, 837 F.2d 1071, 1075, 5 U.S.P.Q.2d 1596, 1600 (Fed. Cir. 1988) (“teachings of references can be combined only if there is some suggestion or incentive to do so.”) (emphasis in original) (quoting *ACS Hosp. Sys., Inc. v. Montefiore Hosp.*, 732 F.2d 1572, 1577, 221 U.S.P.Q. 929, 933 (Fed. Cir. 1984)). The need for specificity pervades this authority. *See, e.g., In re Kotzab*, 217 F.3d 1365, 1371, 55 U.S.P.Q.2d 1313, 1317 (Fed. Cir. 2000) (“particular findings must be made as to the reason the skilled artisan, with no knowledge of the claimed invention, would have selected these components for combination in the manner claimed”); *In re Roufet*, 149 F.3d 1350, 1359, 47 U.S.P.Q.2d 1453, 1457-58 (Fed. Cir. 1998) (“even when the level of skill in the art is high, the Board must identify specifically the principle, known to one of ordinary skill, that suggests the claimed combination. In other words, the Board must explain the reasons one of ordinary skill in the art would have been motivated to select the references and to combine them to render the claimed invention obvious.”)).

- [b] at least one extensible finger coupled to said body portion, the extensible finger being composed of a plurality of retractable segments, the plurality of retractable segments of the extensible finger configured to controllably telescopically extend from the body portion;
- [c] at least one reservoir in communication with said extensible finger; and
- [d] a control circuitry coupled to said extensible finger, and/or said body portion.<sup>10</sup>

As shown following, (1) Examiner is interpreting Stultz to “teach” at least a portion of the text of Independent Claim 1, but has not provided any objectively verifiable evidence supporting her interpretation and (2) modification/combination of Stultz cited by Examiner to meet the recitations of Independent Claim 1 are mere conclusory statements and would change the principle of operation of the prior art components.

Under the MPEP standards as set forth herein, Examiner has not met her burden to establish a *prima facie* case of the unpatentability of Independent Claim 1 for any or all of the forgoing reasons. Accordingly, Applicant respectfully requests that Examiner withdraw the rejections of Claim 1 and Issue a Notice of Allowability for same.

**a) Examiner is Characterizing Stultz to “Teach” the Text of Independent Claim 1, But Does Not Support Her Characterization, Therefore The Examiner Has Not Met Her Burden to Establish a *Prima Facie* Case of Unpatentability for Independent Claim 1**

The Examiner has stated as follows with regards to previously presented Claim 15:

Regarding the above claims, Lebel et al and Labbe et al both teach the device of claim 1 as disclosed above, but fail to teach or disclose that the extensible finger includes a plurality of telescoping segments. However, Stultz discloses a series of hollow telescoping segments in Figure 3A which comprise the extensible finger 14'. At the time of the invention, it would have been obvious to one having ordinary skill in the art to use a telescoping extensible finger such as that disclosed by Stultz because doing so would be a simple substitution of one known

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<sup>10</sup> The lettering of the clauses herein is merely for sake of clarity of argument and should not be taken to imply any particular ordering of the clauses.

element (a non-telescoping catheter for another (a telescoping catheter) in order to achieve a predictable result (drug delivery).

*See Examiner's Office Action, p. 8 (23 June 2009) (emphasis added).*<sup>11</sup>

Applicant respectfully traverses the rejection.

**(1) Examiner Has Put Forth No Evidence Supporting Her Characterization That Stultz "Teaches" Recitations of Independent Claim 1**

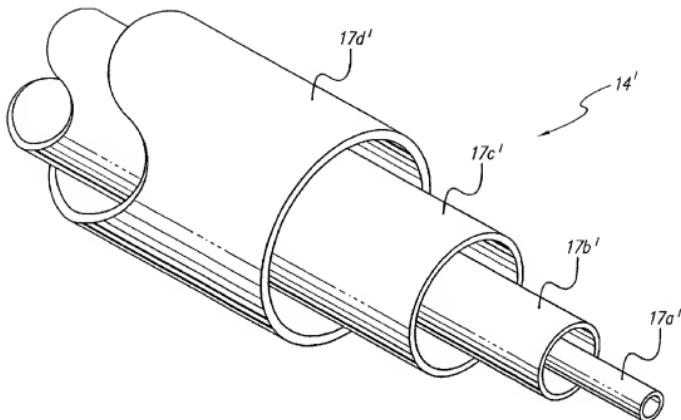
First, Applicant agrees that Lebel and Labbe "fail to teach or disclose that the extensible finger includes a plurality of telescoping segments."

Second, Applicant respectfully points out that Applicant has reviewed the Stultz reference identified by Examiner, and so far as Applicant can discern, Stultz does not recite or suggest "[b] at least one extensible finger coupled to said body portion, the extensible finger being composed of a plurality of retractable segments, the plurality of retractable segments of the extensible finger configured to controllably telescopically extend from the body portion" as recited in Applicant's Independent Claim 1.<sup>12</sup> Rather, the portions of Stultz cited by Examiner actually recite as follows:

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<sup>11</sup> Applicant respectfully asserts that Examiner has apparently not examined the express recitations of Applicant's claims, and hence appears to have inadvertently overlooked the express language of both Applicant's claims and the Examiner-cited technical material. Accordingly, Applicant respectfully maintains that Examiner has not established a *prima facie* case of the unpatentability of any pending claim for at least this reason. Notwithstanding the foregoing, Applicant demonstrates herein that even if Examiner had followed the MPEP examination guidelines, no *prima facie* case of unpatentability would be extant.

<sup>12</sup> Nor does the technical material recite as Examiner alleges, for that matter; Applicant again points out that, in derogation of the MPEP guidelines, Examiner has apparently ignored the language of Applicant's claim at issue.



**FIG. 3A**

See Stultz, Figure 3A.

As can be seen from the foregoing, the Examiner-identified portions of Stultz do not recite or suggest the text of at least Clause [b] of Independent Claim 1: “at least one extensible finger coupled to said body portion, the extensible finger being composed of a plurality of retractable segments, the plurality of retractable segments of the extensible finger configured to controllably telescopically extend from the body portion.” Instead, with regards to Figure 3A referenced by Examiner, Stultz states:

**Each chamber 30a, 30b, . . . 30n has a pump mechanism associated therewith that causes the medication stored in the respective chamber to be dispensed through the respective lumen at a programmed rate and/or at a programmed delivery time.** By way of functional illustration only, the pump mechanism associated with chambers 30a includes a miniature stepping motor M1 that drives a lead screw 37 passing through an anchored lead nut 35. A distal end of the lead screw 37 attaches to movable diaphragm 36, which diaphragm forms one wall of the chamber 30a. As the lead screw 37 rotates a fixed rotational amount, under control of the stepper motor M1, the distal end of the lead screw, and hence the

diaphragm 36, advances a fixed amount, causing a fixed volume of medication within chamber 30a to be dispensed through lumen 17a.

In a similar manner, additional miniature stepper motors M2, M3, . . . Mn, control respective lead screws coupled to movable diaphragms of chambers 30b, 30c . . . 30n, thereby allowing controlled volumes of medication stored in chambers 30b, 30c . . . 30n to be dispensed through lumens 17b, 17c . . . 17n, respectively.

An alternative embodiment of a multi-lumen catheter 14' that may be used with the invention is illustrated in FIG. 3A. Such alternative embodiment includes multiple coaxial lumens 17a', 17b', 17c' and 17d'. As seen in FIG. 3A, the lumen 17a' has the smallest diameter, and fits within the lumen 17b'. The lumen 17b' similarly fits within the lumen 17c', and the lumen 17c' fits within the lumen 17d'. Such alternative embodiment of a coaxial multi-lumen catheter 14' may have different volumes associated with each lumen, thereby facilitating the dispensing of different volumes of fluid or other medications at the same time. That is, the actual volume remaining within each lumen 17a', 17b', 17c' or 17d' for delivery of a medication, after subtracting out the volume occupied by the other coaxial lumens, may differ significantly. In contrast, a multi-lumen catheter 14 (seen best in FIG. 4) shows multi-lumens of more or less the same diameter, all contained within the same sheath. Of course, multi-lumens contained within the same sheath could also have different diameters, as needed or desired for a given application.

*See Stultz, Paragraphs 0033, 0034, and 0041 (emphasis added).*

Thus, Clause [b] recites *inter alia* “the plurality of retractable segments of the extensible finger configured to controllably telescopically extend from the body portion” and Stultz recites “multiple coaxial lumens 17a', 17b', 17c' and 17d' ... facilitating the dispensing of different volumes of fluid or other medications at the same time.” Consequently, on its face, Stultz does not show the text of at least Clause [b] of Independent Claim 1.

Applicant respectfully notes: “[W]hat a reference teaches is a question of fact.” *Amazon.com, Inc. v. Barnesandnoble.com, Inc.*, 239 F.3d 1343, 1358 (Fed. Cir. 2001) (referencing *In re Beattie*, 974 F.2d 1309, 1311 (Fed.Cir.1992)). See also *McGinley v. Franklin Sports*, 262 F.3d 1339, 1350 (Fed. Cir. 2001).

Applicant respectfully submits that there is no PROFFERED EVIDENCE THAT WOULD SUPPORT A finding of fact that Stutz describes or teaches the text of Clauses [e] and [b] of Independent Claim 1. Under the guidelines from the *MPEP* and from the case law established by the Court of Appeals for the Federal Circuit, as set forth above, the cited art of record fails to suggest Independent Claim 1 for at least these reasons.

Applicant has shown by direct quotations that Independent Claim 1 and the Examiner-cited Stultz reference are very different on their faces. Insofar that Applicant has shown that “*at first sight; on the first appearance; on the face of it; so far as can be judged from the first disclosure*” the Examiner-cited art is very different from Claim 1, and Applicant has noted that Examiner has not cited to any objectively verifiable evidence/argument based on same sufficient to remedy such *prima facie* differences, the Examiner-cited technical material does not a establish a *prima facie* case of the unpatentability of Claim 1 either under the *MPEP* or under controlling legal standards.

Accordingly, insofar as that Stultz does not recite the text of at least Clause [b] of Applicant’s Independent Claim 1, and insofar as that Examiner has provided no objectively verifiable evidence, or argument based on objectively verifiable evidence, as to how Stultz could be modified/combined to teach at least Clause [b] of Independent Claim 1, Applicant respectfully points out that under the *MPEP* guidelines as set forth above, the Examiner-cited technical material does not a establish a *prima facie* case of the unpatentability of Independent Claim 1 for at least these reasons. Thus, Applicant respectfully asks Examiner to hold Independent Claim 1 allowable and to issue a Notice of Allowability of same.

With respect to Examiner assertions regarding the teachings of Stultz, Applicant demonstrated above that the express recitations of Stultz are not as Examiner alleges, and that Examiner has provided no evidence—let alone the preponderance of the evidence required—to support Examiner assertions as to the factual conclusion as to what Stultz “teaches.” Accordingly, Applicant respectfully points out that in view of the foregoing, Examiner has presented no evidence that Stultz teaches as asserted by Examiner. In addition, Applicant respectfully points out that even if Examiner’s assertions regarding the teachings of Stultz were supported, such would be of no moment in that Examiner has yet to connect the alleged teaching of Stultz to the actual express language of Applicant’s Independent Claim 1. Under the *MPEP* guidelines as set forth above, the cited art of record fails to establish a *prima facie* case of

unpatentability for at least these reasons. Accordingly, for at least the foregoing reasons, Applicant respectfully requests that Examiner hold Independent Claim 1 allowable and issue a Notice of Allowability of same.

**(2) Examiner Interpretation Appears to be Based on Inadvertent Impermissible Hindsight, Personal Knowledge, or Official Notice; Applicant Requests Issuance of Notice of Allowability**

Given that Applicant has shown, above, what Stoltz actually recites, the question thus naturally arises as to how Examiner saw Stoltz as “teaching” something related to Clause [b] of Independent Claim 1. Applicant respectfully points out that the Applicant’s Application is the only objectively verifiable Examiner-cited document of record that shows or suggests what Examiner purports the references to teach. From this and the express recitations of Stoltz as set forth, it follows that Examiner is interpreting Stoltz through the lens of Applicant’s application, which is impermissible hindsight use. Thus, at present, Examiner’s assertions regarding Stoltz are untenable. Under the MPEP guidelines as set forth above, the cited art of record fails to establish a *prima facie* case<sup>13</sup> of unpatentability for at least these reasons. Accordingly, for at least the foregoing reasons, Applicant respectfully requests that Examiner hold Independent Claim 1 allowable and issue a Notice of Allowability of same.

In the alternative and/or in addition to the foregoing, as Examiner has provided no objectively verifiable evidence, nor argument based on objectively verifiable evidence, in support of Examiner assertions regarding what the technical material cited by Examiner “teaches,” Applicant infers that the Examiner is relying on “personal knowledge” and/or is taking “official notice” of one or more factors to reach the factual conclusion of what the cited technical material “teaches.” In view of the foregoing, if Examiner desires to maintain the rejection, in the next communication, Applicant respectfully requests that the Examiner provide an affidavit or declaration setting forth objectively verifiable evidence in support of Examiner’s currently unsupported assertions regarding what the cited technical material “teaches” and/or should be interpreted to “teach.” *See, e.g., MPEP S 2144.03(C), If Applicant Challenges a Factual*

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<sup>13</sup> Specifically, *prima facie* is defined as “at first sight; on the first appearance; on the face of it; so far as can be judged from the first disclosure.” *Black’s Law Dictionary* p. 1189 (6<sup>th</sup> ed. 1990).

*Assertion as Not Properly Officially Noticed or Not Properly Based Upon Common Knowledge, the Examiner Must Support the Finding with Adequate Evidence, and 37 C.F.R. 1.104(d)(2).*

**b) Modifications/Combinations to Meet the Recitations of Independent Claim 1 Change the Principle of Operation of Components of Cited References; No Teaching to Combine/Modify Components as a Matter of Law.**

In addition and/or in the alternative to the foregoing, Applicant additionally points out that, not only has Examiner failed to adduce any objectively verifiable evidence sufficient to support a teaching to modify/combine Stultz to meet the recitations of Independent Claim 1, there can be no such teaching as a matter of law. Specifically, shown following is that under the MPEP standards there can be no teaching to modify/combine the technology of Stultz because any proposed modification/combination would change the principle of operation of the technology.

**(1) Modifications to Meet the Recitations of Independent Claim 1 Change the Principle of Operation of Components Being Modified; No Teaching to Modify/Combine Components as a Matter of Law.**

In addition and/or in the alternative to the foregoing, Applicant additionally points out that, not only has Examiner failed to adduce any objectively verifiable evidence sufficient to support Examiner assertions regarding an alleged teaching to modify/combine Stultz to meet the recitations of Independent Claim 1, there can be no such teaching as a matter of law. Specifically, Applicant respectfully points out that MPEP § 2143.01, Suggestion or Motivation to Modify the References, citing *In re Ratti*, 270 F.2d 810, 123 USPQ 349 (CCPA 1959), expressly states that “[i]f the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious.”

Applicant respectfully asserts that modification of Stultz would change the principle of operation of the cited reference. For example, Stultz states, “As seen in FIG. 3A, the lumen 17a' has the smallest diameter, and fits within the lumen 17b'. The lumen 17b' similarly fits

**within the lumen 17c', and the lumen 17c' fits within the lumen 17d'. Such alternative embodiment of a coaxial multi-lumen catheter 14' may have different volumes associated with each lumen, thereby facilitating the dispensing of different volumes of fluid or other medications at the same time.**” *See Stultz*, Para 0041 (emphasis added).

As indicated above, Applicant respectfully submits that Stultz fails to disclose “**the plurality of retractable segments of the extensible finger configured to controllably telescopically extend from the body portion**” and that modifying the disclosure of Stultz would change the principle of operation of Stultz. Specifically, Stultz cannot be modified from “**a coaxial multi-lumen catheter 14' may have different volumes associated with each lumen, thereby facilitating the dispensing of different volumes of fluid or other medications at the same time**” into a “**plurality of retractable segments of the extensible finger configured to controllably telescopically extend from the body portion**” without “substantial reconstruction and redesign of the elements shown in [Stultz] as well as a change in the basic principle under which [Stultz] construction was designed to operate.” MPEP § 2143.01 (IV) (citing *In re Ratti*, 270 F.2d 810, 813, 123 USPQ 349, 352 (CCPA 1959)). Accordingly, if the rejection is maintained, Applicant respectfully requests that Examiner provide objectively verifiable evidence sufficient to support Examiner’s assertions regarding any alleged teaching to modify Stultz.

Applicant respectfully submits that not only has Examiner failed to provide a teaching to modify Stultz to meet the recitations of Independent Claim 1, there can be no such teaching as a matter of law for at least the above stated reason. Applicant asserts that under the MPEP standards as set forth above, Examiner has not established a *prima facie* case that the art of record renders Independent Claim 1 unpatentable. Applicant respectfully asks Examiner to hold Independent Claim 1 allowable and to issue a Notice of Allowance of same.

**2. Dependent Claims 2-34 and 66-68 Patentable for at Least Reasons of Dependency from Independent Claim 1**

Claims 2-34 and 66-68<sup>14</sup> depend either directly or indirectly from Independent Claim 1. “A claim in dependent form shall be construed to incorporate by reference all the limitations of the claim to which it refers.” *See* 35 U.S.C. § 112 paragraph 4. Consequently, Dependent Claims 2-34 and 66-68 are patentable for at least the reasons why Independent Claim 1 is patentable. Accordingly, Applicant respectfully requests that Examiner hold Dependent Claims 2-34 and 66-68 patentable for at least the foregoing reasons, and issue a Notice of Allowability on same.

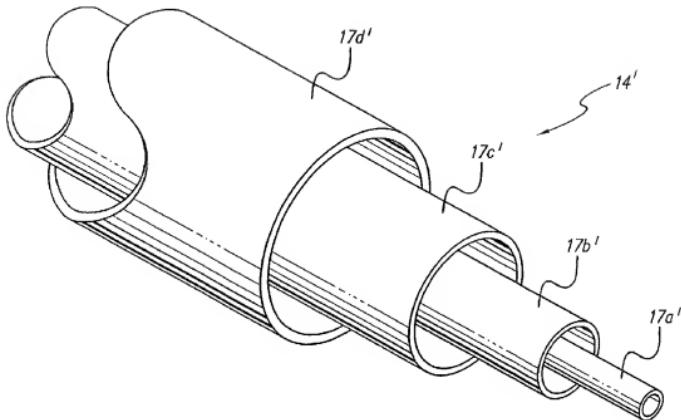
**3. Dependent Claim 15 is Independently Patentable**

Irrespective of the arguments discussed above, Claim 15 is independently patentable. Applicant respectfully points out that Applicant has reviewed the Stultz reference identified by Examiner, and so far as Applicant can discern, Stultz does not recite or suggest “wherein the plurality of retractable segments are configured to articulate at joints of adjacent segments.” as recited in Dependent Claim 15.<sup>15</sup> Instead, Stultz illustrates:

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<sup>14</sup> In relation to these dependent claims, Examiner has provided no objectively verifiable evidence, nor argument based on objectively verifiable evidence, in support of Examiner assertions regarding what the technical materials “disclose.” Insofar as none of these literally recite what Examiner asserts that they “disclose,” Applicant respectfully asserts that Examiner must have relied on “personal knowledge” or taken improper “official notice” of one or more factors to reach each of these assertions. Applicant accordingly requests an appropriate affidavit or declaration in support of any of these rejections that are to be maintained, including any considerations purported to reflect what is “well known in the art.” *See, e.g.*, 37 C.F.R. 1.104(d)(2).

<sup>15</sup> *See* 35 U.S.C. § 112 paragraph 4 (“A claim in dependent form shall be construed to incorporate by reference all the limitations of the claim to which it refers.”).



**FIG. 3A**

*See Stultz, Figure 3A.*

Consequently, on its face, Stultz does not show the text of Dependent Claim 15. Applicant has shown that on its face the evidence cited by Examiner does not establish a *prima facie* case of unpatentability with respect to Claim 15. Applicant has shown by direct quotations that Applicant's Claim 15 and the Examiner-cited Stultz reference are very different on their faces. Insofar that Applicant has shown that *"at first sight; on the first appearance; on the face of it; so far as can be judged from the first disclosure"* the Examiner-cited art is very different from Dependent Claim 15 and its parent claim, and Applicant has noted that Examiner has not cited to any objectively verifiable evidence/argument based on same sufficient to remedy such *prima facie* differences, the Examiner-cited technical material does not establish a *prima facie* case of the unpatentability of Dependent Claim 15 and its parent claim either under the MPEP or under controlling legal standards as set forth above.

Accordingly, and insofar as that Examiner has provided no objectively verifiable evidence, or argument based on objectively verifiable evidence, as to how Stultz could be

modified/combined to teach Dependent Claim 15, Applicant respectfully points out that under the MPEP guidelines as set forth above, the Examiner-cited technical material does not establish a *prima facie* case of the unpatentability of Dependent Claim 15 for at least these reasons. Thus, Applicant respectfully asks Examiner to hold Dependent Claim 15 allowable and to issue a Notice of Allowability of same.

#### 4. Dependent Claim 67 is Independently Patentable

Irrespective of the arguments discussed above, Claim 67 is independently patentable. Applicant respectfully points out that Applicant has reviewed the Stultz reference identified by Examiner, and so far as Applicant can discern, Stultz does not recite or suggest “wherein a length of the at least one extensible finger is controllably adjustable.” as recited in Dependent Claim 67.<sup>16</sup> Instead, Stultz illustrates a length of coaxial multi-lumen cable 14 as follows:

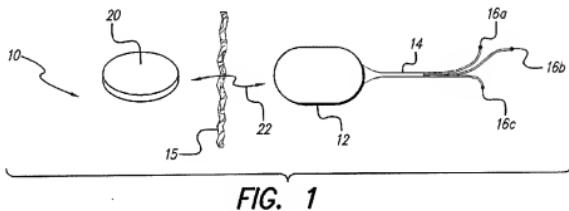


FIG. 1

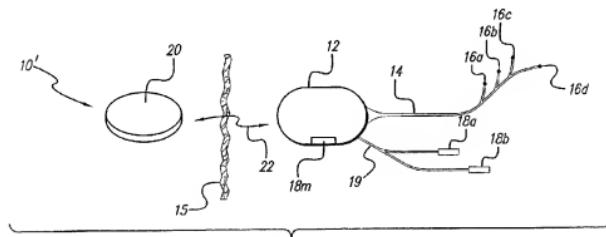
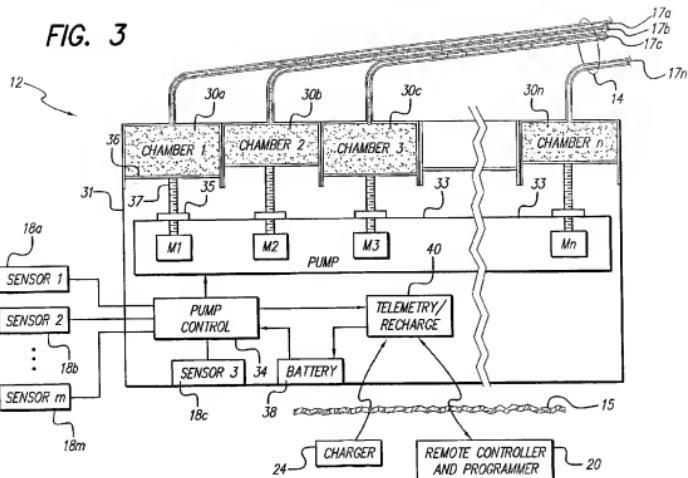


FIG. 2

<sup>16</sup> See 35 U.S.C. § 112 paragraph 4 (“A claim in dependent form shall be construed to incorporate by reference all the limitations of the claim to which it refers.”).

FIG. 3



See Stultz, Figures 1, 2, and 3.

Consequently, on its face, Stultz does not show the text of Dependent Claim 67. Applicant has shown that on its face the evidence cited by Examiner does not establish a *prima facie* case of unpatentability with respect to Claim 67. Applicant has shown by direct quotations that Applicant's Claim 67 and the Examiner-cited Stultz reference are very different on their faces. Insofar that Applicant has shown that *"at first sight; on the first appearance; on the face of it; so far as can be judged from the first disclosure"* the Examiner-cited art is very different from Dependent Claim 67 and its parent claim, and Applicant has noted that Examiner has not cited to any objectively verifiable evidence/argument based on same sufficient to remedy such *prima facie* differences, the Examiner-cited technical material does not establish a *prima facie* case of the unpatentability of Dependent Claim 67 and its parent claim either under the MPEP or under controlling legal standards as set forth above.

Accordingly, and insofar as that Examiner has provided no objectively verifiable evidence, or argument based on objectively verifiable evidence, as to how Stultz could be

modified/combined to teach Dependent Claim 67, Applicant respectfully points out that under the MPEP guidelines as set forth above, the Examiner-cited technical material does not establish a *prima facie* case of the unpatentability of Dependent Claim 67 for at least these reasons. Thus, Applicant respectfully asks Examiner to hold Dependent Claim 67 allowable and to issue a Notice of Allowability of same.

##### 5. Dependent Claim 68 is Independently Patentable

Irrespective of the arguments discussed above, Claim 68 is independently patentable. Applicant respectfully points out that Applicant has reviewed the Stultz reference identified by Examiner, and so far as Applicant can discern, Stultz does not recite or suggest “wherein articulation of the at least one extensible finger is controllably adjustable,” as recited in Dependent Claim 68.<sup>17</sup> Instead, Stultz illustrates coaxial multi-lumen cable 14 as follows:

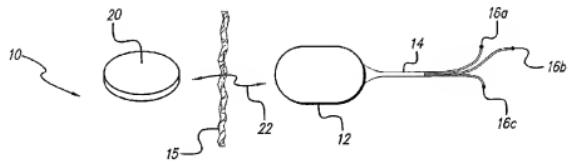


FIG. 1

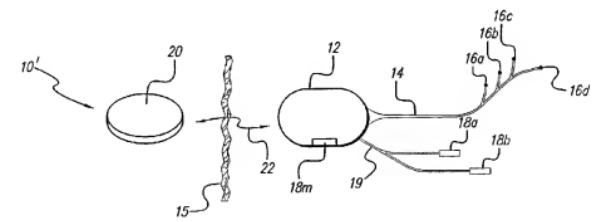
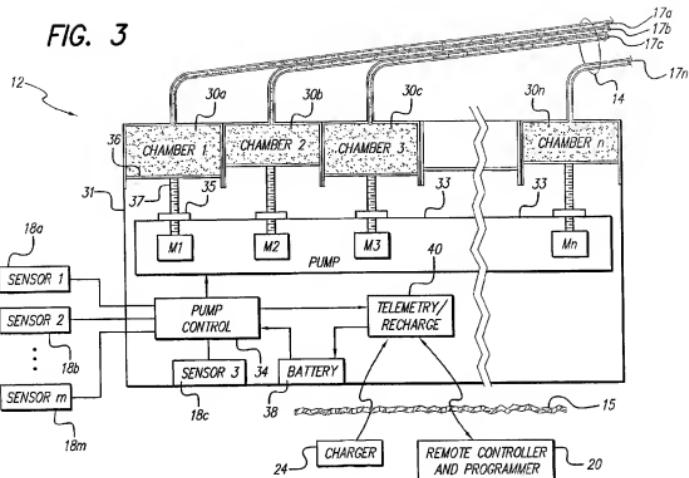


FIG. 2

<sup>17</sup> See 35 U.S.C. § 112 paragraph 4 (“A claim in dependent form shall be construed to incorporate by reference all the limitations of the claim to which it refers.”).

FIG. 3



See Stultz, Figures 1, 2, and 3.

Consequently, on its face, Stultz does not show the text of Dependent Claim 68. Applicant has shown that on its face the evidence cited by Examiner does not establish a *prima facie* case of unpatentability with respect to Claim 68. Applicant has shown by direct quotations that Applicant's Claim 68 and the Examiner-cited Stultz reference are very different on their faces. Insofar that Applicant has shown that *"at first sight; on the first appearance; on the face of it; so far as can be judged from the first disclosure"* the Examiner-cited art is very different from Dependent Claim 68 and its parent claim, and Applicant has noted that Examiner has not cited to any objectively verifiable evidence/argument based on same sufficient to remedy such *prima facie* differences, the Examiner-cited technical material does not establish a *prima facie* case of the unpatentability of Dependent Claim 68 and its parent claim either under the MPEP or under controlling legal standards as set forth above.

Accordingly, and insofar as that Examiner has provided no objectively verifiable evidence, or argument based on objectively verifiable evidence, as to how Stultz could be

modified/combined to teach Dependent Claim 68, Applicant respectfully points out that under the MPEP guidelines as set forth above, the Examiner-cited technical material does not establish a *prima facie* case of the unpatentability of Dependent Claim 68 for at least these reasons. Thus, Applicant respectfully asks Examiner to hold Dependent Claim 68 allowable and to issue a Notice of Allowability of same.

## **VII. CONCLUSION**

Applicant may have during the course of prosecution cancelled and/or amended one or more claims. Applicant notes that any such cancellations and/or amendments will have transpired (i) prior to issuance and (ii) in the context of the rules that govern claim interpretation during prosecution before the United States Patent and Trademark Office (USPTO). Applicant notes that the rules that govern claim interpretation during prosecution form a radically different context than the rules that govern claim interpretation subsequent to a patent issuing. Accordingly, Applicant respectfully submits that any cancellations and/or amendments during the course of prosecution should be held to be tangential to and/or unrelated to patentability in the event that such cancellations and/or amendments are viewed in a post-issuance context under post-issuance claim interpretation rules.

Insofar as that the Applicant may have during the course of prosecution cancelled/amended claims sufficient to obtain a Notice of Allowability of all claims pending, Applicant may not have during the course of prosecution explicitly addressed all rejections and/or statements in Examiner's Office Actions. The fact that rejections and/or statements may not be explicitly addressed during the course of prosecution should NOT be taken as an admission of any sort, and Applicant hereby reserves any and all rights to contest such rejections and/or statements at a later time. Specifically, no waiver (legal, factual, or otherwise), implicit or explicit, is hereby intended (e.g., with respect to any facts of which Examiner took Official Notice, and/or for which Examiner has supplied no objective showing, Applicant hereby contests those facts and requests express documentary proof of such facts at such time at which such facts may become relevant). For example, although not expressly set forth during the course of prosecution, Applicant continues to assert all points of (e.g. caused by, resulting from, responsive to, etc.) any previous Office Action, and no waiver (legal, factual, or otherwise), implicit or explicit, is hereby intended. Specifically, insofar as that Applicant does not consider the

cancelled/unamended claims to be unpatentable, Applicant hereby gives notice that it may intend to file and/or has filed a continuing application in order prosecute such cancelled/unamended claims.

With respect to any cancelled claims, such cancelled claims were and continue to be a part of the original and/or present patent application(s). Applicant hereby reserves all rights to present any cancelled claim or claims for examination at a later time in this or another application. Applicant hereby gives public notice that any cancelled claims are still to be considered as present in all related patent application(s) (e.g. the original and/or present patent application) for all appropriate purposes (e.g., written description and/or enablement). Applicant does NOT intend to dedicate the subject matter of any cancelled claims to the public.

Should this case go to appeal, Applicant reserves the right to submit argument, rebuttal evidence, or legal authority in the instance the Board of Patent Appeals and Interferences finds that the Examiner has met her burden in establishing a *prima facie* case of unpatentability of the various appealed claims. Applicant further reserves the right to submit argument, rebuttal evidence, or legal authority if new claim interpretations or definitional citations are raised on appeal. The fact that argument, rebuttal evidence, or legal authority may not have been explicitly discussed during the course of prosecution should NOT be taken as an admission or waiver of any sort, and Applicant hereby reserves any and all rights to discuss (e.g. make explicit, produce, or explain) such rebuttal evidence at a later time.

The Examiner is encouraged to contact the undersigned by telephone at 206-838-6400 to discuss the above and any other distinctions between the claims and the applied references, if desired. Also, if the Examiner notes any informalities in the claims, he is encouraged to contact the undersigned to expediently correct such informalities.

Respectfully submitted,

/James J. Ruttler, 56,919/

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